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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,326	08/30/2001		Martin Gleave	UBC.P-020-2	2324
21121	7590	10/03/2003		EXAMINER	
OPPEDAH P O BOX 50		ARSON LLP	LACOURCIER	LACOURCIERE, KAREN A	
DILLON, CO 80435-5068				ART UNIT	PAPER NUMBER
				1635	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	09/944,326	GLEAVE ET AL.					
Office Action Summary	Examiner	Art Unit					
•	Karen A. Lacourciere	1635					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on							
,	is action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
4)⊠ Claim(s) <u>1-27</u> is/are pending in the application.							
, , , , , , , , , , , , , , , , , , , ,	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) <u>1-27</u> are subject to restriction and/or e	election requirement.						
Application Papers							
9)☐ The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) D Notice of Informal F	r (PTO-413) Paper No(s) Patent Application (PTO-152)					

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 3, 9, 16 and 19, drawn to an oligonucleotide sequence composition of SEQ ID NO:4, classified in class 536, subclass 24.5.
- II. Claims 4, 10, 17, and 20, drawn to an oligonucleotide sequence composition of SEQ ID NO:5, classified in class 536, subclass 24.5.
- III. Claims 5, 11, 18, and 21, drawn to an oligonucleotide sequence composition of SEQ ID NO: 12, classified in class 536, subclass 24.5.

Claims 1, 2, 6-8, 12-15, and 22-27 link(s) inventions I and II and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 6-8, 12-15 and 22-27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

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provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons: Inventions I and II and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to compositions comprising separate and distinct oligonucleotide sequences.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the antisense sequences claimed are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434), however, given the increased search burden placed on the Office and the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences, Applicant is required to select one (1) sequence composition for examination on the merits.

The instant application specifically claims antisense SEQ ID NOS 4, 5 and 12, which are targeted to and modulate the expression of TRPM-2. Although the antisense sequences claimed each target and modulate expression of the same gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following

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reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of TRPM-2 mRNA, and each antisense, upon binding to TRPM-2, functionally modulates the expression of TRMP-2 to a varying degree. Furthermore, a search of more than one (1) of the antisense sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) antisense sequence, SEQ ID NO:4, 5 or 12, set forth as Group I or II or III respectively.

Because these inventions are distinct for the reasons given above and the search required for each of Groups I or II or III is not required for each of the other Groups, and each Group has a separate and distinct search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 7:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere September 30, 2003

KAREN A. LACOURCIERE, PH.D.
PRIMARY EXAMINER